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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/760,380	01/16/2001	Bernard Belleau	IAF-1/2 C11	2480

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EXAMINER
MCKENZIE, THOMAS C

ART UNIT	PAPER NUMBER
1624	12

DATE MAILED: 10/10/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/760,380	BELLEAU ET AL.	
	Examiner	Art Unit	
	Thomas McKenzie Ph.D.	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-75* is/are pending in the application.

4a) Of the above claim(s) *51-54 and 73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-50,55-63,65-69,74 and 75* is/are rejected.

7)☒ Claim(s) *64 and 70-72* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to an election filed on 8/9/02. There are forty-one claims pending and thirty-six under consideration. Claims 35-72, 74, and 75 are synthesis claims. This is the second action on the merits. The application concerns some 1,3,5-triazine compounds and synthesis thereof.

Election/Restrictions

2. Applicant's election with traverse of Group III, the 1,3,5-triazines in Paper No. 11 is acknowledged. The traversal is on three grounds. Firstly, the different heterocyclic rings are equivalent. Secondly, that the rings are chemically equivalent. Thirdly, that in the art of nucleoside chemistry it is common to group all the rings together. This is not found persuasive because firstly the non-equivalence of the differing rings is *prima facie* established by the differing classifications, MPEP §803. Secondly, Applicants are claiming synthesis of 5-membered azole compounds, 5-membered monohetero pyrrole compounds, six-membered pyridine compounds, six-membered diazines, and triazines. According to Paquette (Principles of Modern Heterocyclic Chemistry) the azoles are intermediate in reactivity between pyrroles and pyridines, page 194, final paragraph. Thus, all three heterocycles are art-recognized as differing. On page 223, the electron deficient nature of pyridine is "the major factor in the observed reactivity differences [from other heterocycles]". In the first complete paragraph

on page 309, the lesser basicity of diazines is taught as a result "which the second nitrogen atom conveys to the heterocyclic system." Thus, all the differing rings are art recognized as chemically nonequivalent. Thirdly, the elected triazine heterocycle is not found in the naturally occurring nucleosides. The oxathiolane ring is not a naturally occurring sugar. Thus, the artisan who would be concerned with Applicants' process is a synthetic organic chemist, not a biochemist concerned with nucleosides and would not classify all the rings together.

Applicants' presented no data in support of their arguments. Assertion is not argument. Applicants' fifteen inventions are distinct because of the different chemical structures. A reference anticipating Group I would not necessarily make obvious Group II-XV and vice versa. According, the requirement is still deemed proper and is therefore made FINAL.

3. Claims 51-54 and 73 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group of inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 11.

4. Objection is made to claims 35-50, 55-72, 74, and 75 as containing non-elected subject matter. The compounds and claimed synthetic methods that make

them present a variable core. Claims 35, 36, 45, 46, 55, 56, 63, 64, 74, and 75 contains formulas drawn to the non-elected inventions.

5. Claims 63 and 64 both contain below formula (XVI) reference to non-elected purine and pyrimidine bases.

Claim Objections

6. Claims 35, 45, 55, 63, 74, and 75 are objected to because of the following informalities: the first triazine in claim 35 has four bonds to nitrogen and the second a missing hydrogen atom. The only triazine in claims 45, 55, and 63 has a missing hydrogen atom. The first triazine in claim 74 has four bonds to nitrogen and the second has a missing hydrogen atom. The first triazine in claim 75 has a missing hydrogen atom, the second has four bonds to nitrogen, and the third a missing hydrogen atom. Appropriate correction is required.

7. Claims 63, 64, and 75 are objected to because of the following informalities: the formula (XVI) in all three claims appears to be mislabeled. On page 13, Scheme 1 the compound with ester R_w is labeled (XIV). The formula (XVI) on page 18 has a different ester group.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 35, 37, 39-41, 45, 47, 48, 55, 57-59, 63, 65-69, 74, and 75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claims 35, 45, 55, 63, 74, and 75 the words "thioaryl", "thiol", and "thioalkyl" occur. These are all indefinite. The term "thioalkyl" is indefinite for it is not clear if the bond from the thioalkyl group is from the sulfur or the alkyl. If the inventors intend the group HSR-, the Examiner suggests the word "mercaptoalkyl". If they intend the group RS-, then the word "alkylthio" is appropriate. The term "thiol" is indefinite because it refers to a group of compounds not a monovalent radical. If the inventors intend the group HS-, Examiner suggests the word "mercapto". Does "thioaryl" refer to a thiophene or to an aryl group with a side chain sulfur? If the later, it is not clear if the bond from the thioaryl group is from the sulfur or the aryl. If the inventors intend the group HSC_6H_4-, the Examiner suggests the word "mercaptoarylene". If they intend the group C_6H_5S-, then the word "arylthio" is appropriate.

To the extent that variables R_7 and R_8 are not used for the claimed triazines, the Examiner suggests deleting these definitions.

9. Claims 37, 38, 65, and 66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly

claim the subject matter which applicant regards as the invention. In claims 37, 38, 65, and 66 the phrase "or aromatic C_{1-6} acyl" is indefinite. What do Applicants mean by an aromatic group with a single carbon atom? While the Examiner knows what a six carbon aromatic group is, does an aromatic C_6 acyl group include the carbonyl carbon atom in the carbon count? If so, then what is a five carbon aromatic group?

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 35-44, 55, 57-59, and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 35, 36, 55, and 74 the protecting ester group R_y has changed to R_7 in formula (XVI) and back again to R_y in formula (XVII). On page 18, Scheme 2 Applicants have pictured formula (XVI) with the ester group R_y. R_7 can be cyano halogen etc. How did this transformation occur?

11. Claims 35-44, 55, 57-59, and 74 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the

specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As explained above, Applicants have different formulas (XVI) pictured on page 18 and in the claims.

12. Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claims 45 and 46 the oxidation state of the side chain carbon atom has mysteriously changed from formula (XXII) to formula (XXIII). Formula (XXIII) has this carbon atom in the acid oxidation state and each process requires it to be reduced to a hydroxymethyl group. In Scheme 3, on page 23 Applicants have formula (XXIII) with the correct oxidation state but with a different protecting group on this hydroxymethyl group. How is this oxidation achieved?

13. Claims 45-50 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As

explained above, Applicants have different formulas (XXIII) pictured on page 23 and in the claims.

14. Claims 56 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. In claim 56, the protecting ester group R_y has changed to R_7 in formulas (XVI) and formula (XVII). On page 18, Scheme 2 Applicants have pictured both formula (XVI) and formula (XVII) with the ester group R_y. R_7 can be cyano halogen etc. How did this transformation occur?

15. Claims 56 and 60-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. As explained above, Applicants have different formulas (XVI) and (XVII) pictured on page 18 and in the claims.

Allowable Subject Matter

16. The following is a statement of reasons for the indication of allowable subject matter: Applicants claims are novel over Liotta ('466) who teaches coupling of oxathiolane compounds containing the hydroxymethyl side chain with

pyrimidines but not the triazines of the present application. Applicants' claims do not conflict with Belleau ('008) who claims coupling of oxathiolane compounds containing the carboxylic ester side chain with pyrimidines and purines but not the triazines of the present application. Similarly, the present claims do not conflict with he claims of Belleau ('806), who claims synthesis of oxathiolane compounds containing the hydroxymethyl side chain with pyrimidine compounds but not the triazines of the present application.

Conclusion

17. Please direct any inquiry concerning this communication or earlier communications from the Examiner to Thomas C McKenzie, Ph. D. whose telephone number is (703) 308-9806. The FAX number for before final amendments is (703) 872-9306. The Examiner is available from 8:30 to 5:30, Monday through Friday. If attempts to reach the Examiner by telephone are unsuccessful, you can reach the Examiner's supervisor, Mukund Shah at (703) 308-4716. Please direct general inquiries or any inquiry relating to the status of this application to the receptionist whose telephone number is (703) 308-1235.

RICHARD L. RAYMOND
PRIMARY EXAMINER

Mukund Shah
Supervisory Patent Examiner
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TCMcK
October 4, 2002

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